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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,033	12/04/2003	Stephen F. Badylak	3220-73985	8358

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EXAMINER

SCHUBERG, LAURA J

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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08/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/728,033</p>	<p>Applicant(s) BADYLAK, STEPHEN F.</p>	
	<p>Examiner Laura Schuberg</p>	<p>Art Unit 1657</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 August 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-16.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Continuation of 11. does NOT place the application in condition for allowance because: the claims remain rejected under the prior art.

Applicant argues that the references do not suggest the specific element of removing endotoxins from the graft compositions and thus do not render obvious the claimed invention.

This is not found persuasive because the WO 98/25637 document specifically states that the process of removing the cellular elements from the tissue allows the preparation of a graft composition that is non-immunogenic, and thus does not induce a host immune response when implanted into a host (page 3 lines 3-10). Clearly this process would also remove any endotoxins as well as they would also elicit an immune response if left with the tissue. Applicant's disclosure also suggests that the process of removing the cellular components also removes the endotoxins as well (page 4 lines 18-25 of the as filed specification). At the very least the endotoxins would be removed upon the sterilization of the composition as taught by the WO 98/25637 (page5).

Applicant argues that the '123 patent can not be properly combined with the WO 98/25637 document because the '123 patent teaches the removal of the glycoproteins and thus teaches away from the WO 98/25637 and the current claimed invention which require glycoproteins.

This is not found persuasive because the WO 98/25637 teaches that proteins, including glycoproteins, that facilitate cellular proliferation can be added back into the basement composition (page 11 lines 16-20). The '123 patent only suggests the removal of those glycoproteins that would cause an antigenic response, not that glycoproteins could not be added back in to the composition as suggested by WO

98/25637. Clearly many antigenic components (cells, glycoproteins, growth factors) are removed during the preparation of the basement membrane and then new components added back in a form more suitable for the intended method of repair. Therefore the reference teachings are compatible for combination as the '123 patent does not require that glycoproteins that do not elicit an immune response (such as those added back into the composition as taught by WO 98/25637) be absent from the final composition.

Applicant's arguments with regard to the double patenting rejections are identical to those presented above and are therefore also not found persuasive as well.

Therefore the claims remain rejected as obvious over the prior art..